

## REMARKS

Claims 11 and 18-20 have been amended. Claims 21 and 22 are new. Claims 11-22 will be pending in this application upon entry of this amendment. Applicants respectfully request reconsideration of the rejections of these claims for the reasons set forth below.

### **35 USC § 112**

Applicants request reconsideration of the rejection of claims 11-20 under 35 U.S.C. § 112, first paragraph. Applicants have amended the claims to remove the subject matter identified in the rejection. Accordingly, the Section 112 rejection has been overcome and the rejection should be withdrawn.

### **Allowable Subject Matter**

Claims 18-20 were identified as being allowable in the Office action dated November 30, 2009. Claims 18-20 have been rewritten in independent form to recite subject matter deemed allowable by the Examiner. Accordingly, Applicant requests claims 18-20 be allowed.

### **35 USC § 102 - prior Office action**

In the action dated November 30, 2009, the Office rejected claims 11-15 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 7,264,351 (Shadduck '351) or U.S. Patent 7,278,739 (Shadduck '739). This rejection was withdrawn in view of the Section 112 rejection. As the Section 112 rejection has been overcome, Applicant re-addresses the Section 102 rejection.

Each of the claims recites multi-focal contact lens wherein the lens is manufactured at least partially from a responsive polymer gel capable of continuous changes in shape. As would be understood by one of ordinary skill in the art, "continuous" as used in the claim does not mean that the lens always changes shape. Rather, it would be understood that once the lens reaches a shape required to provide a particular focal shape, the lens will stay at that shape as long as required but will

change to a different shape (and hence a different focus) when a different stimulus is applied.

The claims as amended explicitly recite responsive gel polymers. Further, the claims highlight a primary advantage, namely permitting the shape of the lens to be continuously changeable in response to a stimulus. As disclosed in the specification at paragraph [0028], this element allows the user to focus at several desired distances. In contrast, the Shadduck lenses disclosed in the cited references use shape memory polymers that are dual shape (see e.g., Shadduck '351, col. 5 lines 56-7), and fail to disclose the possibility of achieving a range of shapes and corresponding focal lengths. Applicant's responsive polymers, as described in the specification, do not "store" any shape in memory or remember an original shape to which they could return by either applying or withdrawing a stimulus. When used in a lens of the present invention, these polymers provide the benefit of constantly changing shape during use to correct presbyopia. In other words, this feature enables a lens user to focus not only at a particular long distance point and a particular short distance point, but also any other point. Hence, responsive polymers, central to their responsive nature, do not store any shape memory.

A particular advantage of the lens of the present invention is that a single focus is provided at any one given time but the focus may be changed over time when needed. This is in direct contrast to the Shadduck references where aberrations are corrected via a large number of micro actuators which each produce different foci at any one given time. For example, the abstract of Shadduck '351 which states, "[T]he invention can be used to create highly localized surface corrections in the lens to correct higher order aberrations [and] also can provide spherical corrections in the lens."

The claims of the present application require that the changes can be continuous, i.e., able to occur throughout the life of the lens. This enables different single foci to be supplied by the lens at different times to correct presbyopia. Thus, the present invention allows for a succession of applying and reversing the deformation. This is in direct contrast to the teaching in the Shadduck references which allows for a one time modification of the characteristics of the lens to correct any error in the

prescription. It should also be noted the Shadduck references suggest the optical characteristics should be permanently fixed after this initial modification.

Both Shadduck summaries of invention state, "[T]he actuators of the present invention differ completely as that they only need to be actuated one time, or perhaps a few times, and there is no need for rapid actuation response time." As one skilled in the art would appreciate, Shadduck's reference to a few times means until the correct correction has been achieved at which point the lens is fixed and not the ability to continue to change throughout the life of the lens. Thus, Shadduck is in fact the direct opposite of the present invention. It does not enable an infinite number of changes of focus over time nor does it allow for the rapid response times which are an inherent feature of the present invention and which are a requirement if the product is going to be acceptable to the user.

To support these remarks, Applicants resubmits herewith the April 2007 article published in the "Materials Today" Journal describing how shape memory polymers change their shape in a pre-defined way from shape A to shape B, where shape B is selected by applying a process called "programming". When a stimulus is provided, the polymer will move between shape A and shape B but will not move to any other shape, and fails to realize the benefits of the applicant's claimed invention as described above. The article is not offered as prior art, but as evidence of how shape memory polymers change shape.

In view of the foregoing, Applicant requests the 35 U.S.C. § 102 rejection be withdrawn.

**35 USC § 103 - prior Office action**

In the action dated November 30, 2009, the Office rejected claims 16 and 17 under 35 U.S.C. § 103(a) as being obvious over Shadduck '351 or Shadduck '739 in view of U.S. Patent 5,712,721 (Large). This rejection was withdrawn in view of the Section 112 rejection. As the Section 112 rejection has been overcome, Applicant re-addresses the Section 103 rejection. Even when combined with either Shadduck reference, Large fails to cure the deficiencies of Shadduck stated above. Accordingly, applicants request that the 35 USC § 103 rejection be withdrawn

Further, both Shadduck references state, "When the shaped SMP is cooled below the melting point or glass transition temperature of the soft segment while the shape is deformed, that temporary shape is fixed." This is a teaching away from the present invention. If the shape becomes fixed in the lens of the present invention the entire system fails. It is an essential feature that there can be successive rapid lens shape changes. Accordingly, applicants request that the 35 U.S.C. § 103 rejection be withdrawn.

### **New Claims**

New independent claim 21 recites a multi-focal contact lens wherein the lens is manufactured at least partially from a responsive polymer gel, **said lens capable of changes in shape with stimulus during use**. The Shadduck references, on the other hand, disclose extreme heating processes during lens manufacture for switching between the two memory shapes of the lenses, a process that logically cannot be carried out when in use on the eye. Independent claim 21 further recites that the stimulus is selected from the group consisting of temperature, pH, ionic strength, light, electric field, magnetic field, shear forces, and a chemical trigger. Shadduck does not disclose, and is further inoperable, to deliver a stimulus during use as reasoned above. Benefits of the Applicants claimed approach manage to do so without affecting patient comfort and viability.

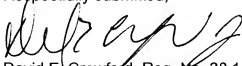
New claim 22 recites a multi-focal contact lens wherein the lens is manufactured at least partially from a **responsive polymer gel capable of changing shape over time**.

### **Conclusion**

Applicants respectfully request allowance of the claims for the reasons set forth above.

The Commissioner is hereby authorized to charge the fee for 2-month extension of time, the fee for two additional independent claims, and any other fees in connection with this response, to Deposit Account No. 19-1345.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David E. Crawford', is written over the typed name.

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